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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,652	01/22/2005	Oleg Iliich Epshteni	841/9	8482

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,652	EPSHTENI ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008 and 10 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-12* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to ILIA OUSPENSKI, Group Art Unit 1644, Technology Center 1600.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 10/28/2008 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2008 has been entered.

3. Applicant's amendment and remarks filed on 10/28/2008 and 12/10/2008 are acknowledged.

Claims 2 and 3 have been canceled.
Claims 7 – 12 have been added.

Claims 1 and 4 – 12 are pending.

Claims 4 and 5 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 04/20/2007.

Claims 1 and 6 – 12 are presently under consideration.

4. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments.

It is noted that New Grounds of Rejection are set forth herein.

5. Applicant and the assignee of this application are required under **37 CFR 1.105** to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

An issue of public use or on sale activity has been raised in this application. Specifically, in an interview with Examiners S. Wen and P. Gambel on 11/20/2008 Applicant's representative demonstrated an exhibit of tablets comprising the instantly claimed medicament and indicated that the tablets were on sale in Russia, as evidenced by the Interview Summary.

In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows:

Applicant is required to furnish a statement detailing whether the claimed medicament or a substantially similar preparation was in public use or on sale in this country more than one year prior to the date of application for patent in the United States. It is noted that to constitute the public use of an invention it is not necessary that more than one of the patent articles should be publicly used, nor is it necessary that more than one person use the invention. See MPEP 2133.03(a). Further, a sale is deemed to have occurred if there was a definite sale, or offer to sell, more than 1 year before the effective filing date of the U.S. application and the subject matter of the sale, or offer to sell, fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art. See MPEP 2133.03(b).

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

The time period for reply to this requirement coincides with the time period for reply to this Office Action.

6. Regarding potential issues of New Matter under 35 USC 112, first paragraph, the following is noted.

Applicant has amended the claims to recite a "homeopathically activated" form of an antibody. The instant specification as-filed contains a disclosure at page 1, sixth paragraph, of "an activated (potentized) form of monoclonal, polyclonal, or natural antibodies to interferon." The specification further discloses at page 2, last paragraph, "a preparation containing homeopathically potentized polyclonal sheep antibodies to murine interferon alpha." Taken together, and considered in view of Applicant's arguments at pages 4 – 5 of the response of 10/28/2008 and pages 2 - 3 of the response of 12/10/2008, this disclosure is deemed to provide adequate support of the newly added recitation for the purposes of New Matter.

7. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 6 – 12 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of the claimed method, because Applicant is not in possession of a "homeopathically activated form" of antibodies to interferon.

It is apparent that "homeopathically activated" antibodies are an essential part of the instant claimed invention. However, the specification does not appear to provide a sufficient written description of the process of homeopathically activating antibodies to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification discloses at page 2 several distinct and apparently conflicting methods of treating antibodies, such as "consecutive multiple dilutions," "impact of an external mechanical factor," "multiple vertical shaking," and "exposure to ultrasonic, electromagnetic, or ther physical factors." These diverse treatments are do not appear to have a known or disclosed common mechanism of action that would result in "activating" antibodies; therefore, the skilled artisan cannot envision the contemplated "homeopathic activation" of antibodies.

Applicant's disclosure further appears to rely on the publication of Shvabe W. (Homoopathisches Arzneibuch, 1978), cited at page 2, for written description of homeopathic activation. However, the publication does not appear to have been incorporated by reference, and further, "essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the

Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

9. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1, 7, and 10 – 12 are rejected under **35 U.S.C. 102(a)** as being anticipated by Epshtein et al. (WO 01/97842, published 12/27/2001; see entire document) as evidenced by US Pat. Pub. No. 2003/0099636 (see entire document).

It is noted that WO 01/97842 is a publication of International Application PCT/RU01/00239, while US Pat. Pub. No. 2003/0099636 is a publication of application USSN 10/311,666. The latter US application is a national stage entry of PCT/RU01/00239 and as such contains the same disclosure.

Epshtein et al. teach homeopathically potentiated antibodies to gamma interferon (e.g. Example 39 at paragraphs 0345 – 0347 of US Pat. Pub. No. 2003/0099636), and administration of said antibodies to a patient (ibid.), i.e. a medicament.

Therefore, the teachings of the reference anticipate the instant claimed invention.

11. Conclusion: no claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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February 9, 2009

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